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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 09/804,408 | 03/12/2001 | Mathew F. Ogle | 1416.20US01 | 1108 |
| 22865 | 7590 | 09/08/2004 | EXAMINER | |
| ALTERA LAW GROUP, LLC 6500 CITY WEST PARKWAY SUITE 100 MINNEAPOLIS, MN 55344-7704 | | | NAFF, DAVID M | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1651 | |

DATE MAILED: 09/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) |
|------------------------------|------------------------|---------------------|
| | 09/804,408 | OGLE ET AL. |
| Examiner | Art Unit | |
| David M. Naff | 1651 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

THE MAILING DATE OF THIS COMMUNICATION:

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 18 June 2004.

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-9, 11-28 and 34-43 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) Claim(s) _____ is/are allowed.
6) Claim(s) 1-9, 11-28 & 34-43 is/are rejected.
7) Claim(s) _____ is/are objected to.
8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) Notice of References Cited (PTO-892)
2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ .
5) Notice of Informal Patent Application (PTO-152)
6) Other: _____

DETAILED ACTION

The amendment of 6/18/04 amended claims 1, 16, 22, 34, 36 and 42, and cancelled claim 10. While claim 42 is indicated as amended, the change is not indicated.

5 Claims examined on the merits are 1-9, 11-28 and 34-43, which are all claims in the application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

10 The following is a quotation of the second paragraph of 35 U.S.C. 112:

15 The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

20 Claims 1-9, 11-28 and 34-43 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

25 The recitation, "generally non-reactive", in line 4 of claim 1 and where recited in other claims, is uncertain as to meaning and scope. It is uncertain as to an amount of non-reactivity required and reactivity excluded by the term "generally". This term is vague, and its metes and bounds are relative and subjective.

The claims are further unclear by "the functional groups" in claim 1 (line 3), and where recited in other claims, not having clear

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antecedent basis. It is suggested that claim 1 be amended in line 2 by changing "bridges bonded" to --- bridges having functional groups bonded by the functional groups ---. A corresponding change should be made to the other independent claims reciting "the functional groups 5 of the bridges".

Response to Arguments

In regard to reciting "generally", applicants state that comparative reactivity of functional groups of organic molecules is widely understood, and therefore general non-reactivity does not 10 render the claims indefinite.

However, this known reactivity of functional groups does not make the term, "generally" definite since the known reactivity depends on the functional groups being either reactive or not reactive, and not on being "generally" reactive.

Claim Rejections - 35 USC § 103

Claims 1-9, 11-28 and 34-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ogle et al (5,958,669) in view of Yang et al (5,935,168) for reasons in the previous office action of 2/18/04 and for reasons herein.

The claims are drawn to tissue containing linkers bonded to tissue and bridge molecules bonded between two or more of the linkers, to a method of crosslinking tissue to prepare the tissue having linkers and bridge molecules, to tissue containing modified sites having bridge molecules bonded to two or more of the modified sites, 25 and to a method of crosslinking tissue to prepare the tissue having

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modified sites and bridge molecules. In all these embodiments, functional groups of the bridges are required to be generally non-reactive with other bridges.

Ogle et al disclose crosslinking tissue to fix tissue by reacting 5 the tissue with glutaraldehyde.

Yang et al disclose crosslinking tissue with glutaraldehyde, and then reacting with a diamine followed by reacting with additional glutaraldehyde (col 1, line 43 and claims 8-10).

After reacting with glutaraldehyde as disclosed by Ogle et al, it 10 would have been obvious to react with a diamine and then with additional glutaraldehyde as suggested by Yang et al. This will result in the diamine being a linker and the glutaraldehyde being bridge. Additionally, after initially crosslinking with glutaraldehyde some free aldehyde groups will remain that will react 15 with the diamine and result in the glutaraldehyde being a linker and the diamine being a bridge. The aldehyde groups of a glutaraldehyde are generally non-reactive with other aldehyde groups of another glutaraldehyde, and the amine groups of a diamine will not react with amine groups of another diamine. This will result in a bridge not 20 reacting with another bridge.

Response to Arguments

Applicant's arguments filed 6/18/04 have been fully considered but they are not persuasive.

Applicants urge that glutaraldehyde cannot be a bridge since it 25 is known that glutaraldehyde self-polymerizes to form oligomers and

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polymers, and Ogle et al teach that crosslinking compounds such as dialdehydes can polymerize spontaneously in solution under a variety of conditions.

This argument is unpersuasive since polymerizing of the

5 dialdehyde occurs only under certain conditions, and conditions can be controlled such that it does not occur or such that it occurs to an extent to be generally non-reactive. Additionally, this self-polymerizing is not due to covalent bonding between functional groups but is due to attractive forces between bonds similar to adsorption.

10 Therefore, functional groups of a glutaraldehyde molecule will not be expected to covalently react with the functional groups of another glutaraldehyde molecule. Moreover, the general non-reactivity of the claims is after the bridge is reacted with the linkers. This can result from reactive groups of the bridges not being available after 15 reacting with the linkers. The claims do not exclude functional groups of the bridges reacting non-covalently by attractive forces with other bridges in solution prior to the bridge molecules reacting with the linkers bonded to tissue. Furthermore, as set forth above, when reacting glutaraldehyde with tissue as disclosed by Ogle et al 20 and then reacting with a diamine as suggested by Yang et al, the diamine can be the bridge and glutaraldehyde the linker.

Applicants state that dependent claims are unobvious, but gives no reason why these claims are unobvious other than glutaraldehyde self-polymerizing. As set forth above, this argument is unpersuasive.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension 5 of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after 10 the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX 15 MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David M. Naff whose telephone number is 571-272-0920. The examiner can normally be reached on Monday-Friday 9:30-6:00.

20 If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for 5 unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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David M. Naff
Primary Examiner
Art Unit 1651

DMN
9/7/04